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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,119	04/16/2004	Toyoko Kusama	NANP119US	1349
7590 03/30/2010				
Gregory Turocy Amin & Turocy, LLP 24th Floor, National City Center 1900 East 9th Street Cleveland, OH 44114			EXAMINER CHUNDURU, SURYAPRABHA	
			ART UNIT 1637	PAPER NUMBER
			MAIL DATE 03/30/2010	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/826,119

Applicant(s)

KUSAMA ET AL.

Examiner

Suryaprabha Chunduru

Art Unit

1637

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 1-23,26-34,36 and 37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24,25 and 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 April 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. The Applicants' response to the office action field on December 30, 2009 has been considered and acknowledged.

Status of the application

2. Currently claims 24-25, and 35 are pending under examination. Claims 1-23, 26-34, 36-37 were previously withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group. Applicants' arguments and the amendment have been fully considered and deemed unpersuasive for the reasons that follow.

Response to arguments:

3. With regard to the rejection of claims 24-25, and 35 under 35 USC 103(a) as being unpatentable over Saulle et al. in view of Lowe et al., Applicants' arguments and the amendment were fully considered and found unpersuasive. Applicants argue that the Lowe et al. reference is 20 years old and the claimed primers would not be among the output from the Lowe program and assert that the claimed primers are structurally different from the primers generated by using Lowe et al. computer program. The arguments were found unpersuasive. First, as noted in MPEP 2145, "The mere age of the references is not persuasive of the unobviousness of the combination of their teachings, absent evidence that, notwithstanding knowledge of the references, the art tried and failed to solve the problem." In re Wright, 569 F.2d 1124, 1127, 193 USPQ 332, 335 (CCPA 1977) (100 year old patent was properly relied upon in a rejection based on a combination of references.). See also Ex parte Meyer, 6 USPQ2d 1966 (Bd. Pat. App. & Inter. 1988) (length of time between the issuance of

prior art patents relied upon (1920 and 1976) was not persuasive of unobviousness), accordingly the arguments drawn to the age of the Lowe et al. reference were found unpersuasive. Second, the computer program for designing primers from a known sequence is the basis for obviousness rejection but not on the actual sequences shown by Lowe et al. reference. In the instant situation Saulle et al. reference does teach a known sequence that comprises the claimed primer sequence, and it is obvious to an ordinary person skilled in the art, to use the known sequence as taught by Saulle et al. to generate primers or primer pairs using the computer program taught by Lowe et al.

On page 9-10 of the response, Applicants assert that Saulle et al. did not teach the sequences of the claimed primers and indicate that the Board suggests that one skilled in the art would have been able to identify primers within the larger sequence and assert that one skilled in art would find structural similarity from Saulle et al. sequences but not the exact identity of claimed primers. The arguments were fully considered. Examiner notes that Applicants while agreeing for the Board statement that Saulle et al. teach a larger sequence comprising said primer sequences, disagree that the sequences of the primers is not known. The assertions were found unpersuasive because it is clear from the Saulle et al. reference that the sequence comprising said exact primer sequences is known and by applying the computer program of Lowe et al. one of the ordinary person skilled in the art would generate a number of primers or primer pairs that would obviously output the claimed primers.

With regard to the arguments drawn to unexpected results that are not obvious and support for the unexpected results having advantageous and superior properties by the declaration under 1.132, the arguments and the declaration were fully considered and found

unpersuasive. First, In the recent court decision *In Re Deuel* 34 USPQ 2d 1210 (Fed. Cir. 1995), the court determined that the existence of a general method of identifying a specific DNA does not make the specific DNA obvious. Regarding structural or functional homologs, however, the court stated "Normally, a *prima facie* case of obviousness is based upon structural similarity, i.e., an established structural relationship between a prior art compound and the claimed compound. Structural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds. For example, a prior art compound may suggest its homologs because homologs often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties." (Since the claimed primers simply represent structural homologs of the sequences of the prior art sequence of Saulle et al., and concerning which a biochemist of ordinary skill would attempt to obtain alternate compounds with improved properties, the claimed primers and primer pairs are *prima facie* obvious over the cited references. Second, as MPEP 716.02 (d) states "Whether the unexpected results are the result of unexpectedly improved results or a property not taught by the prior art, the "objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support." In other words, the showing of unexpected results must be reviewed to see if the results occur over the entire claimed range. In *re Clemens* , 622 F.2d 1029, 206 USPQ 289, 296 (CCPA 1980)". Here, the unexpected result (supported by the declaration) for the claimed primers is not commensurate in scope with the claims, which is drawn to any ruminant animal derived DNA.

With regard to the arguments drawn to genus does not make species obvious, the arguments were found unpersuasive because as noted in MPEP 2131.02 a genus does not always

anticipate a claim to a species within the genus. However, when the species is clearly named, the species claim is anticipated no matter how many other species are additionally named. Ex parte A, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990) (The claimed compound was named in a reference which also disclosed 45 other compounds. The Board held that the comprehensiveness of the listing did not negate the fact that the compound claimed was specifically taught. A GENERIC CHEMICAL FORMULA WILL ANTICIPATE A CLAIMED SPECIES COVERED BY THE FORMULA WHEN THE SPECIES CAN BE "AT ONCE ENVISAGED" FROM THE FORMULA When the compound is not specifically named, but instead it is necessary to select portions of teachings within a reference and combine them, e.g., select various substituents from a list of alternatives given for placement at specific sites on a generic chemical formula to arrive at a specific composition, anticipation can only be found if the classes of substituents are sufficiently limited or well delineated. Ex parte A, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990). If one of ordinary skill in the art is able to "at once envisage" the specific compound within the generic chemical formula, the compound is anticipated. In the instant situation, the claimed primer sequence within the larger sequence taught by Saulle et al., is anticipated, which is the basis for obviousness rejection, since genus represents the specific species claimed and it is obvious to generate said specific species using the computer program to select the specified species from the genus as taught by Lowe et al. Accordingly for the reasons set forth as above, the rejection is maintained.

Conclusion

No claims are allowable.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30 P.M., Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

//Suryaprabha Chunduru/

Primary Examiner, Art Unit 1637